

AMENDMENTS TO THE CLAIMS

1-48 (Canceled).

49 (Currently Amended). A method of for treating on demand a condition associated with secretion of gastric acid, wherein an oral pharmaceutical dosage form according to claim 1 is administered in a therapeutically effective amount to an individual human or animal afflicted with said condition at least one symptom of gastro-esophageal reflux disease (GERD) comprising

- (i) identifying a proton pump inhibitor or a salt thereof (PPI) selected from a group consisting essentially of acid-activated agents that inhibit the gastric H⁺,K⁺-ATPase enzyme,
- (ii) identifying an H₂ receptor antagonist or a salt therefore (H₂RA) selected from a group consisting essentially of agents that inhibit action of histamine on H₂ receptors on parietal cell surfaces,
- (iii) adopting an oral dose regime comprising:
 - (a) selecting an oral dosage form for the H₂RA for release of H₂RA in a gastro-intestinal tract;
 - (b) selecting an oral dosage form for the PPI for release of PPI in the gastro-intestinal tract and that, when orally administered to the gastro-intestinal tract concomitantly with the H₂RA, delays and/or extends the release of the PPI relative to the release of the H₂RA;
 - (c) orally administering concomitantly the selected oral dosage forms of the H₂RA and the PPI to affect a rise in gastric pH to above about 3 within about 2 hours of administration,
- (iv) on demand, based upon an occurrence of at least one symptom of GERD, orally administering the selected oral dosage forms of the PPI and the H₂RA concomitantly according to the dose regime to affect a rise in gastric pH to above about 3 within about 2 hours of administration, thereby treating at least one symptom of GERD promptly, and
- (v) repeating (iv) on demand, based upon a subsequent occurrence of at least one symptom of GERD, if necessary over a prolonged period.

50-86 (Canceled).

87 (New). A method as claimed in claim 49, wherein (iii)(a) and (iii)(b) comprise selecting separate oral dosage forms for the H2RA and the PPI, and wherein (iii)(c) and (iv) comprises orally administering the separately oral dosage forms concomitantly on demand.

88 (New). A method as claimed in claim 87, wherein the separate oral dosage form for the PPI comprises a tablet or capsule within which the PPI is presented as a plurality of small dosage units comprising pellets, granules or beads distributed within the tablet or capsule.

89 (New). A method as claimed in claim 49, wherein (iii)(a) and (iii)(b) comprise combining the oral dosage forms for the H2RA and the PPI into a single oral dosage form, and wherein (iii)(c) and (iv) comprises orally administering the single oral dosage form on demand.

90 (New). A method as claimed in claim 88, wherein the single oral dosage form comprises a tablet or capsule within which the PPI is presented as a plurality of small dosage units comprising pellets, granules or beads distributed within the tablet or capsule.

91 (New). A method as claimed in claim 90, wherein the tablet or capsule further comprises a pharmaceutically acceptable excipient.

92 (New). A method as claimed in claim 91, wherein the pharmaceutically acceptable excipient comprises a disintegrant.

93 (New). A method as claimed in claim 87 or 89, wherein the PPI is selected from lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, their pharmaceutically acceptable salts, enantiomers and salts of enantiomers, and/or the H2RA is selected from cimetidine, ranitidine, nizatidine and famotidine, their pharmaceutically acceptable salts, isomers and salts of isomers.

94 (New). A method as claimed in claim 89, wherein the single oral dosage form includes a core comprising the PPI and a membrane including an excipient applied onto the core that delays and/or extends the release of the PPI relative to the release of the H2RA.

95 (New). A method as claimed in claim 94, wherein the single oral dosage form includes an alkaline-reacting substance admixed with the PPI.

96 (New). A method as claimed in claim 94, wherein single oral dosage form comprises a tablet or capsule within which the core and the membrane are presented as a plurality of small dosage units comprising pellets, granules or beads distributed within the tablet or capsule.

97 (New). A method as claimed in claim 94, wherein the single oral dosage form comprises two halves, one of which comprises one or more of the cores and membranes, and the other half comprises the H2RA.

98 (New). A method as claimed in claim 97, wherein the H2RA half includes a pharmaceutically acceptable excipient.

99 (New). A method as claimed in claim 98, wherein the pharmaceutically acceptable excipient comprises a disintegrant.

100 (New). A method as claimed in claim 97 or 98, wherein the H2RA forms an outer layer applied onto the membrane of the core.

101 (New). A method as claimed in claim 94, wherein the H2RA forms an outer layer applied onto the membrane of the core, and wherein the single dosage form includes an alkaline-reacting substance admixed with the PPI.

102 (New). A method as claimed in claim 94, wherein the single dosage form includes an enteric coating layer applied onto the membrane.

103 (New). A method as claimed in claim 102, wherein the single dosage form includes a layer separating the enteric coating from the membrane.

104 (New). A method as claimed in claim 102 or 103, wherein the H2RA forms an outer layer applied onto the membrane of the core.

105 (New). A method as claimed in claim 89, wherein the single oral dosage form includes a matrix comprising the PPI and an excipient incorporated with the PPI to delay and/or extend the release of the PPI relative to the release of the H2RA.

106 (New). A method as claimed in claim 105, wherein the single oral dosage form includes an alkaline-reacting substance admixed with the PPI.

107 (New). A method as claimed in claim 105, wherein single oral dosage form comprises a tablet or capsule within which the matrix is presented as a plurality of small dosage units comprising pellets, granules or beads distributed within the tablet or capsule.

108 (New). A method as claimed in claim 105 or 107, wherein the H2RA forms an outer layer applied onto the matrix.

109 (New). A method as claimed in claim 105, wherein the H2RA forms an outer layer applied onto the matrix, and wherein the single oral dosage form includes an alkaline-reacting substance admixed with the PPI.

110 (New). A method as claimed in claim 105, wherein the single oral dosage form comprises two halves, one of which comprises the matrix, and the other half comprises the H2RA.

111 (New). A method as claimed in claim 110, wherein the H2RA half includes a pharmaceutically acceptable excipient.

112 (New). A method as claimed in claim 111, wherein the pharmaceutically acceptable excipient comprises a disintegrant.

113 (New). A method as claimed in claim 105, wherein the single dosage form includes an enteric coating layer applied onto the matrix.

114 (New). A method as claimed in claim 113, wherein the single dosage form includes a layer separating the enteric coating from the matrix.

115 (New). A method as claimed in claim 113 or 114, wherein the H2RA forms an outer layer applied onto the matrix.

116 (New). A method as claimed in claim 49, wherein at least one of the selected oral dosage forms further comprises an antacid agent and/or an alginate.

117 (New). A method as claimed in claim 116, wherein the antacid agent comprises at least one of aluminum hydroxide, calcium carbonate, magnesium carbonate, basic magnesium carbonate, magnesium hydroxide, magnesium oxide and/or sodium hydrogen carbonate.